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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,760	10/09/2001	Shannon Roberts	MIC-005 (109272.150)	8318

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/974,760	ROBERTS ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *77-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *77-135* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of a preliminary amendment filed on December 31, 2002. In the amendment, claims 1-76 were cancelled, and new claims 77-135 were added.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 77-98 and 132-135, drawn to an isolated polypeptide comprising a mutation in the amino acid sequence of SEQ ID NO: 91, wherein the mutation is selected from the group consisting of a change to a Group 2 amino acid at position 31, a Group 5 amino acid at position 41, a Group 2 amino acid change at position 52, a Group 3 amino acid change at position 52, a Group 5 amino acid change at position 73, a Group 4 amino acid change at position 101, a Group 3 amino acid change at position 101, a Group 2 amino acid change at position 111, a Group 2 amino acid change at position 133, a Group 2 amino acid change at position 141, a Group 5 amino acid change at position 141, a Group 6 amino acid change at position 153, a Group 5 amino acid change at position 153, a Group 1 amino acid change at position 281, a Group 2 amino acid change at position 367, a Group 6 amino acid change at position 367, a Group 4 amino acid change at position 389, a Group 2 amino acid change at position 389, classified in class 530, subclass 350.

II. Claims 99-125, drawn to an isolated nucleic acid encoding a polypeptide comprising a mutation in the amino acid sequence of SEQ ID NO: 91, wherein

the mutation is selected from the group consisting of a change to a Group 2 amino acid at position 31, a Group 5 amino acid at position 41, a Group 2 amino acid change at position 52, a Group 3 amino acid change at position 52, a Group 5 amino acid change at position 73, a Group 4 amino acid change at position 101, a Group 3 amino acid change at position 101, a Group 2 amino acid change at position 111, a Group 2 amino acid change at position 133, a Group 2 amino acid change at position 141, a Group 5 amino acid change at position 141, a Group 6 amino acid change at position 153, a Group 5 amino acid change at position 153, a Group 1 amino acid change at position 281, a Group 2 amino acid change at position 367, a Group 6 amino acid change at position 367, a Group 4 amino acid change at position 389, a Group 2 amino acid change at position 389, classified in class 536, subclass 23.1.

III. Claims 126-131, drawn to a method of producing a fungal cell for the production of a secondary metabolite by transforming the fungal cell with an isolated nucleic acid encoding a polypeptide comprising a mutation in the amino acid sequence of SEQ ID NO: 91, wherein the mutation is selected from the group consisting of a change to a Group 2 amino acid at position 31, a Group 5 amino acid at position 41, a Group 2 amino acid change at position 52, a Group 3 amino acid change at position 52, a Group 5 amino acid change at position 73, a Group 4 amino acid change at position 101, a Group 3 amino acid change at position 101, a Group 2 amino acid change at position 111, a Group 2 amino acid change at position 133, a Group 2 amino acid change at position 141, a Group 5 amino acid change at

position 141, a Group 6 amino acid change at position 153, a Group 5 amino acid change at position 153, a Group 1 amino acid change at position 281, a Group 2 amino acid change at position 367, a Group 6 amino acid change at position 367, a Group 4 amino acid change at position 389, a Group 2 amino acid change at position 389, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, Group I is drawn to an isolated polypeptide whose function is to perform a biological activity (in the instant case, the protein is involved in the biosynthesis of lovastatin). The function of the nucleic acid of Group II is to encode a protein, which is a distinct function from the transcriptional regulation of proteins involved in lovastatin biosynthesis. Additionally, the molecular compositions of Groups I and II are chemically distinct, wherein the invention of Group I is comprised of amino acids, whereas invention of Group II is comprised of nucleotides. Because the inventions of Group I and Group II have different functions, and are comprised of distinct chemical building blocks, the inventions represent patentably distinct inventions.

Inventions Group I and Group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct functions and are not disclosed as capable of being used together. The isolated polypeptide of Group I is biologically distinct from an organism expressing said polypeptide (i.e., Group III), and cannot itself be used for the purpose of the organism of Group III (i.e., for the production of a secondary metabolite). Rather, the isolated polypeptide of Group I requires many additional factors in order to be used for the function of the cells (and corresponding method) set forth in Group III. Because these inventions have different functions, they represent patentably distinct inventions.

Inventions Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group II can be used for the distinct purpose of identifying homologues of lovE in additional organisms. AS such, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications

are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER